The Regulations of Connecticut State Agencies are amended by adding section 22a-153-7, as follows:

(NEW)

Sec. 22a-153-7. Radiation Safety Requirements for Therapeutic Radiation Machines, Simulators and Treatment Planning Systems.

(a) Definitions. For the purposes of this section, the definitions of this subsection apply. Terms used in this section that are not defined in this section are as provided in sections 22a-153-1, 22a-153-2 and 22a-153-4 of the Regulations of Connecticut State Agencies.

(1) "AAPM" means American Association of Physicists in Medicine.

(2) "Absorbed dose" or "D" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram, and the special name of the unit of absorbed dose is the gray (Gy).

(3) "Absorbed dose rate" means, for machines with timers, absorbed dose per unit time or, for linear accelerators, dose monitor unit per unit time.

(4) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(5) "ADCL" means Accredited Dosimetry Calibration Laboratory.

(6) "Added filtration" means any filtration that is in addition to the inherent filtration.

(7) "Air kerma" or "K" means the kinetic energy released in air by ionizing radiation measured in joules per kilogram or grays. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM.

(8) "ARRT" means the American Registry of Radiologic Technologists.

(9) "Authorized medical physicist" means a person who:

(A) Meets the requirements of subsection (c)(4) of this section or section 22a-153-8(t) or section 22a-153-8(v) of the Regulations of Connecticut State Agencies; or

(B) Is identified as an authorized medical physicist on a specific medical use license or equivalent permit or registration issued by the Commissioner, NRC or an Agreement State; or

(C) Is identified as an authorized medical physicist on a permit or registration pursuant to a specific medical use license of broad scope issued by the Commissioner, NRC or an Agreement State.

(10) "Authorized user" means a person with the necessary training as identified in subsection (c) of this section to operate an identified piece of equipment regulated by this section.

(11) "Beam axis" means the axis of rotation of the beam limiting device.

(12) "Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

(13) "Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

(14) "Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(15) "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

(16) "Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical or physical process.

(17) "Contact therapy system" means a therapeutic radiation machine with a short target to skin distance, usually less than five (5) centimeters.

(18) "Dose monitor unit," "monitor unit" or "DMU" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(19) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the subject body.

(20) "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

(21) "Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to subsection (f) of this section.

(22) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(23) "Gray" or "Gy" means the SI unit of absorbed dose, kerma and specific energy imparted equal to one joule per kilogram.

(24) "Half-value layer" or "HVL" means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

(25) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(26) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(27) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(28) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(29) "Kilovolt," "kV" or "keV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum, where the abbreviation "kV" applies for photons and the abbreviation "keV" for electrons.

(30) "Lead equivalent" means the thickness of the material in question affords the same attenuation, under specified conditions, as lead.

(31) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(32) "Light field" means the area illuminated by light, simulating the radiation field.

(33) "mA" means milliampere.

(34) “Medical dosimetrist” means a person other than a licensed practitioner who participates in, performs, and/or assists under the supervision of a licensed practitioner and authorized medical physicist in the procedures required in the design, preparation, and evaluation processes for the use of ionizing radiation for therapeutic purposes, and who has met and continues to meet the standard in Section (c)(5) of Sec.22(a)-153-7.

(35) "Megavolt," "MV" or "MeV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum, where "MV" applies for photons and "MeV" for electrons.

(36) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution, including, but not limited to, arc, skip, conformal, intensity modulation and rotational therapy.

(37) "NIST" means the National Institute for Standards and Technology.

(38) "Nominal treatment distance" means:

(A) For electron irradiation, the distance from the scattering foil, virtual source or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam; and

(B) For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(39) "Patient" means a person subjected to machine-produced external beam radiation for the purposes of medical therapy.

(40) "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

(41) "Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

(42) "Phantom" means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question**.**

(43) "Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays, as explained in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Commission on Radiation Units and Measurements, September 15, 1984.

(44) "Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and that will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(45) "Protective barrier" or "barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. Protective barriers are of the following types:

(A) "Primary protective barrier" means the material that attenuates the useful beam for radiation protection purposes and

(B) "Secondary protective barrier" means the material that attenuates stray radiation.

(46) **"**Quality improvement committee" or "QIC" group that reports to or is included in the RSC to review changes as referenced in , but not limited to AAPM report 25, 53, 56 and 73.

(47) "Qualified expert radiation therapy" means:

(A) A medical physicist certified by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

(B) An individual who holds a master's degree or doctor's degree in physics, biophysics, radiological physics, medical physics or health physics and has completed 1 year full time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who is a practicing medical physicist at a medical institution that includes the tasks for which the individual is seeking authorization; and

(C) Has obtained written certification that the individual has satisfactorily completed the requirements listed in paragraph (b) and has achieved a level of competency sufficient to function independently as a medical physicist for each type of therapeutic device for which authorization is requested. The certification must be signed by the authorized preceptor medical physicist.

(48) "Qualified expert radiation safety officer" means:

(A) An individual certified by a specialty board recognized by the Nuclear Regulatory Commission or Agreement State; or

(B) An individual whose training and experience meets the Nuclear Regulatory Commission or Agreement State requirements appropriate for the quantities of radioactive materials possessed, levels of radiation, modes of radiation production and scope of the activities to be conducted.

(49) "Qualified expert radiation shielding design" means:

(A) A health physicist or medical physicist who is competent to design radiation shielding in medical x-ray or radioactive materials imaging/therapeutic facilities. The qualified expert is a person who is certified by the American Board of Health Physics, American Board of Medical Physics, American Board of Radiology or the Canadian College of Physicists in Medicine; or

(B) Is a Radiation Safety Officer or Medical Physicist at a medical institution and has experience in the design of radiation shielding.

(50) "Radiation detector" or "detector" means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(51) "Radiation head" means the structure from which the useful beam emerges.

(52) "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(53) "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

(54) "Scattered primary radiation" means that scattered radiation deviated in direction only by materials irradiated by the useful beam.

(55) "Secondary dose monitoring system" means a system that will terminate irradiation in the event of failure of the primary dose monitoring system.

(56) "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

(57) "Shutter" means a device attached to the tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

(58) "Sievert" or "Sv" means the SI unit of dose equivalent measured in units of joules per kilogram.

(59) "Simulator" or "radiation therapy simulation system" means any X-ray system exclusively used to localize the volume to be exposed during radiation therapy and reproduce the position and size of the therapeutic irradiation field.

(60) "Source" means the region or material from which the radiation emanates.

(61) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(62) "Stray radiation" means the sum of leakage and scattered radiation.

(63) "Target" means that part of an X-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(64) "Target-to-skin distance," "TSD," "source-to-skin distance" or "SSD" means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron-beam focus point to the surface of the irradiated object or patient.

(65) "Tenth-value layer" or "TVL" means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(66) "Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(67) "Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

(68) "Tube" means an X-ray tube, unless otherwise specified.

(69) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

(70) "Useful beam" or "radiation field" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

(71) "Virtual source" means a point from which radiation appears to originate.

(72) "Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

(73) "X-ray tube" means any electron tube designed to be used primarily for the production of X-rays.

(b) Applicability.

(1) This section shall apply to the use of a therapeutic radiation machine by any registrant.

(2) No registrant shall allow the use of a therapeutic radiation machine except by, or under the supervision of, an authorized user satisfying the requirements of subsection (c)(4) of this section.

(3) Equipment used for the sole purpose of radiation therapy simulations shall be exclusively governed by the requirements in Subsection (f) of this section. Equipment used for both diagnostic and therapeutic purposes, shall be subject to the requirements in Subsection (f) of this section in addition to those specified in Sec. 22a-153-4. .

(4) The requirements of subsection (c) of this section do not apply to registrants who use therapeutic radiation machines exclusively for non-human subjects.

(c) General requirements for facilities using therapeutic radiation machines.

(1) Administrative Controls. Each registrant shall be responsible for directing the operation of any therapeutic radiation machine that has been registered with the Commissioner. Each registrant or the registrant's agent shall ensure that the requirements of this section are met in the operation of each therapeutic radiation machine under the registrant's control.

(2) A therapeutic radiation machine that does not meet the provisions of this section shall not be used for irradiation of human patients or human research subjects.

(3) Training for External Beam Radiation Therapy Authorized Users. The registrant for any therapeutic radiation machine subject to subsections (f) or (g) of this section shall require the authorized user to be a physician who meets the requirements of either subparagraph (A) or (B) of this subdivision:

(A) Is certified in:

(i) Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology,

(ii) Radiation oncology by the American Osteopathic Board of Radiology,

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology," or

(iv) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(B) Is in the active practice of therapeutic radiology and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience and a minimum of three (3) years of supervised clinical experience;

(i) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation,

(b) Radiation protection,

(c) Mathematics pertaining to the use and measurement of ionization radiation, and

(d) Radiation biology,

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(a) Review of the full calibration measurements and periodic quality assurance checks,

(b) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings,

(c) Use of administrative controls to prevent medical events,

(d) Implementation of emergency procedures in the event of the abnormal operation of an external beam radiation therapy unit or console, and

(e) Checking and using radiation survey meters, and

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(a) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications,

(b) Selecting proper dose and how it is to be administered,

(c) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation, and

(d) Post-administration follow-up and review of case histories;

(C) Notwithstanding the requirements of subdivision (3)(A) and (B) of this subsection, the registrant for any therapeutic radiation machine subject to subsection (f) of this section may also submit the training of the prospective authorized user physician for the Commissioner's review on a case-by-case basis.

(D) A registrant who satisfies the training requirements of subdivision (3) of this subsection pursuant to subparagraph (B) or (C) shall not allow a physician to act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Commissioner.

(4) Training for An Authorized Medical Physicist. The registrant for any therapeutic radiation machine subject to subsection (f) or (g) of this section shall obtain or utilize the services of an Authorized Medical Physicist and shall require the Authorized Medical Physicist to:

(A) Be registered with the Commissioner as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

(B) Be certified by the American Board of Radiology in:

(i) Therapeutic radiological physics, or

(ii) Roentgen-ray and gamma-ray physics, or

(iii) X-ray and radium physics, or

(iv) Radiological physics; or

(C) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(D) Be certified by the Canadian College of Medical Physics; and

(E) Pursue continuing professional development in accordance with the guidelines from the applicable certification board.

(5) Training for an Authorized Medical Dosimetrist. The registrant for any therapeutic radiation machine subject to subsection (f) or (g) of this section shall obtain or utilize the services of an Authorized Medical Dosimetrist and shall require the Authorized Medical Dosimetrist to:

(A) Be registered with the Commissioner as a provider of radiation services in the area of radiotherapy treatment plan design, preparation, and evaluation under the supervision of a radiation therapy authorized user and authorized medical physicist; and

(B) Be certified by the Medical Dosimetrist Certification Board; and

(C) Pursue continuing professional development in accordance with the guidelines from the Medical Dosimetrist Certification Board.

(D) Dosimetrists not meeting the criteria of an Authorized Medical Dosimetrist may perform duties only under the direct supervision of an Authorized Medical Dosimetrist.

(6) Operators shall have the following qualifications:

(A) Individuals who will be operating a therapeutic radiation machine for medical use shall be ARRT Registered Radiation Therapy Technologists. Individuals who are

not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology; and the names and training of all personnel currently operating a therapeutic radiation machine shall be available at the facility. Information on former operators shall be retained for a period of at least two (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(7) Written safety procedures and rules shall be developed by an Authorized Medical Physicist or Qualified Expert and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(8) Individuals shall not be exposed to the useful beam except for medical therapy purposes unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. No person shall be deliberately exposed for training, demonstration or other non-healing arts purposes.

(9) Visiting Authorized User. Notwithstanding the provisions of this subsection, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to sixty (60) days per calendar year under the following conditions:

(A) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(B) The visiting authorized user meets the requirements established for authorized user(s) in subdivisions (3)(A) and (3)(B) of this subsection; and

(C) The registrant maintains copies of all records specified by this subdivision for five (5) years from the date of the last visit.

(10) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's registration. In addition to the requirements of this section, all individuals associated with the operation of a therapeutic radiation machine are also subject to the applicable requirements of sections 22a-153-2(c) and 22a-153-2(h)(2) of the Regulations of Connecticut State Agencies.

(11) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each therapeutic radiation machine, for inspection by the Commissioner:

(A) Report of acceptance testing;

(B) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this section, as well as the name(s) of person(s) who performed such activities;

(C) Records of maintenance and/or modifications performed on the therapeutic radiation machine performed after the effective date of this section, as well as the names of all persons who performed such services; and

(E) Signature of Authorized Medical Physicist authorizing the return of therapeutic radiation machine to clinical use after service, repair, upgrade, any component replacement or major repair or modification of components that could significantly affect the characteristics of the radiation beam.

(12) Records Retention. All records required by this section shall be retained for a period of five (5) years unless another retention period is specifically authorized in this section. All required records shall be retained in an active file from at least the time of generation until the next inspection by the Department. Any required record generated prior to the last Department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved for five (5) years.

(13) Each licensee or registrant shall implement procedures for auditing the effectiveness of the radiation therapy quality assurance program.

(A) Audits must be conducted at intervals not to exceed four years by an organized review program supervised by the American College or Radiology, American College of Radiation Oncology, or a program found to be equivalent by the Commissioner based on the scope of the audit and the experience of the sponsoring organization in performing such audits.

(B) The licensee or registrant shall promptly review the audit findings, address the need for modifications or improvements and document the actions taken.

(C) Any deficiencies noted during the audit shall be corrected in accordance with appropriate auditing programs standards.

(D) Information submitted to the facilities during the audit and documented corrective actions shall be available for review by the Department.

(d) General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Protection Surveys. Each registrant shall ensure that a radiation protection survey of any new or existing facility not previously surveyed is performed with an operable radiation measurement survey instrument calibrated in accordance with subsection (h) of this section. The radiation protection survey shall be performed by, or under the direction of, an Authorized Medical Physicist or qualified expert and shall verify that, with the therapeutic radiation

machine in a "BEAM ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(A) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in section 22a-153-2(c)(1) of the Regulations of Connecticut State Agencies;

(B) Radiation levels in unrestricted areas do not exceed the limits specified in sections 22a-153-2(d)(1) and (2) of the Regulations of Connecticut State Agencies;

(C) A radiation protection survey shall also be performed under the following circumstances, prior to any subsequent medical use:

(i) After making any change in the treatment room shielding,

(ii) After making any change in the location of the therapeutic radiation machine within the treatment room,

(iii) After relocating the therapeutic radiation machine, or

(iv) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room;

(D) Any protection survey record shall indicate all instances where the facility, in the opinion of an Authorized Medical Physicist or Qualified Expert, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts per hour or millirems per hour adjusted for expected workload, use and occupancy factors; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey; and

(E) If the results of the surveys required by subsections (d)(1)(A) and (B) or subsection (d)(1)(C) of this section indicate any radiation levels in excess of the respective limits specified in subsections (d)(1)(A) and (B) of this section, the registrant shall lock the control in the "OFF" position and not use the unit:

(i) Except as may be necessary to repair, replace or test the therapeutic radiation machine, the therapeutic radiation machine shielding or the treatment room shielding; or

(ii) Until the registrant has received a specific exemption from the Commissioner.

(2) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by subsection (d)(1) of this section indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by sections 22a-153-2(f)(1) and (f)(2)(A) of the Regulations of Connecticut State Agencies, before beginning the treatment program the registrant shall:

(A) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with sections 22a-153-2(f)(1) and (f)(2)(A) of the Regulations of Connecticut State Agencies;

(B) Perform the survey required by subsection (d)(1) of this section again; and

(C) Perform one of the following tasks:

(i) Include in the report required by subsection (d)(1) of this section the results of the initial survey, a description of the modification made to comply with subsection (d)(2)(A) of this section and the results of the second survey, or

(ii) Request and receive a registration amendment under section 22a-153-2(f)(2)(B) of the Regulations of Connecticut State Agencies that authorizes radiation levels in unrestricted areas greater than those permitted by sections 22a-153-2(f)(1) and (f)(2)(A) of the Regulations of Connecticut State Agencies.

(3) Dosimetry Equipment.

(A) Each registrant shall have a calibrated dosimetry system available for use. The dosimetry system shall be calibrated at an energy or energy range appropriate for the radiation being measured. The system shall have been calibrated by NIST or by an AAPM ADCL. The calibration shall have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration; and

(B) Each registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subsection (d)(3)(A) of this section. This comparison shall have been performed within the previous twelve (12) calendar months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in subsection (d)(3)(A) of this section; and

(C) Each registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared or compared as required by subsections (d)(3)(A) and (B) of this section; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison or comparison; and evidence that the intercomparison was performed by, or under the direct supervision of an Authorized Medical Physicist.

(4) Reports of External Beam Radiation Therapy Surveys and Measurements. Each registrant of any therapeutic radiation machine subject to subsections (f) and (g) of this section shall furnish a copy of the records required in . subsections (d)(1) and (d)(2) of this section to the Commissioner within thirty (30) days following completion of the action that initiated the record requirement.

(e) Quality Management Program. Each registrant shall implement a quality management program at each facility under its control. A registrant may use the quality management programs of Appendices B and C of this section.

(f) Radiation therapy simulator machines. Radiological equipment used for simulating radiation therapy delivery techniques shall comply with the following:

(1) General Requirements.

(A) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures in accordance with manufacturer's recommended specifications.

(B) Technique chart. A technique chart relevant to the particular radiation producing machine shall be displayed in the vicinity of the control panel and used by all operators.

(C) No individual other than the patient shall be in the simulation room when the simulator produces ionizing radiation.

(2) Additional Requirements for radiation therapy simulators used in the general radiographic mode of operation.

(A) Beam limitation. The following items shall be evaluated prior to first clinical use and at intervals determined and documented by the Authorized Medical Physicist:

(i) A method to visually define the center of the x-ray field to within a 2 mm diameter.

(ii) A method to accurately determine the source to image distance to within 2 mm.

(iii) The delineator wires shall be accurate with the indicated setting within 2 mm.

(B) Machine movements. The following items shall be evaluated prior to first clinical use and at intervals determined and documented by the Authorized Medical Physicist:

(i) The gantry movements are within 1 degree of the indicated position.

(ii) The collimator movements are within 1 degree of the indicated position.

(C) Timer Reproducibility. When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation shall not exceed 0.05. This parameter shall be evaluated prior to first clinical use and at intervals determined and documented by the Authorized Medical Physicist.

(D) Exposure Reproducibility. When all technique factors are held constant, including control panel selections associated with AEC systems, the coefficient of variation shall not exceed 0.05. This parameter shall be evaluated prior to first clinical use and at intervals determined and documented by the Authorized Medical Physicist.

(E) Linearity. An evaluation of the linearity of the system shall be performed over the clinically appropriate range of use. This parameter shall be evaluated prior to first clinical use and at intervals determined and documented by the Authorized Medical Physicist.

(3) Additional Requirements for computed tomography based radiation therapy simulators. Tomographic systems shall meet the following requirements. All testing shall be performed prior to first clinical use and at intervals determined and documented by the Authorized Medical Physicist, unless otherwise explicitly stated.

(A) Lasers. The gantry laser plane shall be within 2 mm of the imaging plane, and the external lasers (if installed) shall define a plane within 2 mm of the offset distance determined during the initial commissioning. This shall be evaluated for each day of clinical use.

(B) CT number accuracy. The CT number of water shall be 0 +/-5 HU in the center of the scan field of view.

(C) Field Uniformity. The field uniformity shall be evaluated to ensure the values are consistent with the values determined during the initial commissioning.

(D) Table Motion.

(i) Vertical Motion. The motion of the couch in the vertical direction shall be tested to ensure accurate motion over the range used clinically.

(ii) Longitudinal Motion. The motion of the couch in the longitudinal direction shall be tested to ensure accurate motion over the range used clinically.

(E) Warning Lights. Warning lights should indicate the presence of radiation being produced.

(F) Electron density to CT number conversion. An evaluation of the electron density to CT number conversion shall be performed over a complete range of clinically applicable values.

(G) Spatial resolution. An evaluation of the spatial resolution of the system shall be performed.

(H) Contrast resolution. An evaluation of the contrast resolution of the system shall be performed.

(I) Accurate transfer of the data to the treatment planning system. The Authorized Medical Physicist shall validate the accuracy of the transfer of patient data to each radiotherapy planning system in clinical use that is interfaced with the CT simulator.

(g) Therapeutic Radiation Machines of Less Than 500 kV. Each registrant shall operate any therapeutic radiation machine of less than 500 kV according to the requirements of this subsection.

(1) Leakage Radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine, as follows:

(A) For 5-50 kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (100 mrad) in any one hour;

(B) For >50 and <500 kV systems, the leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 cGy (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters when the source is operated at maximum design parameters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour; and

(C) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subsections (f)(1)(A) and (f)(1)(B) of this section for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Commissioner.

(2) Permanent Beam Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or Removable Beam Limiting Devices.

(A) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent (5%) of the useful beam for the most penetrating beam used; and

(B) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter System. The filter system shall be so designed that:

(A) Filters cannot be accidentally displaced at any possible tube orientation;

(B) For equipment installed after the effective date of this section, an interlock system shall prevent irradiation if the proper filter is not in place;

(C) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one meter under any operating conditions; and

(D) Each filter shall be marked as to its material of construction and its thickness.

(5) Tube Immobilization.

(A) The X-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(B) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval as follows:

(A) A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

(B) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. For equipment other than ortho-voltage, after irradiation is terminated and before irradiation can be reinitiated, ; the elapsed time indicator shall be reset;

(C) If any dose monitoring system present has not previously terminated irradiation, the timer shall terminate irradiation when a pre-selected time has elapsed;

(D) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

(E) The timer shall not permit an exposure if set at zero;

(F) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(G) The timer shall be accurate to within one percent of the selected value or one second, whichever is greater.

(9) Control Panel Functions. The control panel, in addition to the displays required by other provisions in this subsection, shall have:

(A) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

(B) An indication of whether X-rays are being produced;

(C) A means for indicating X-ray tube potential and current;

(D) The means for terminating an exposure at any time;

(E) A locking device that will prevent unauthorized use of the therapeutic radiation machine; and

(F) For therapeutic radiation machines manufactured after the effective date of this section, a positive display of each specific filter in the beam.

(10) Multiple Tubes. When a control panel may energize more than one X-ray tube:

(A) It shall be possible for the operator to activate only one X-ray tube at any time;

(B) The control panel shall indicate which X-ray tube is activated; and

(C) The tube housing assembly shall indicate when that tube is energized.

(11) Target-to-Skin Distance. There shall be a means of determining the central axis TSD to within one centimeter and reproducing this measurement to within two millimeters.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(14) In addition to shielding adequate to meet requirements of subsection (i) of this section, any treatment room containing a therapeutic radiation machine capable of operating in the range 50kV-500kV shall meet the following design requirements:

(A) Aural Communication. The treatment room shall provide continuous two-way aural communication between the patient and the operator at the control panel; and

(B) Viewing Systems. The treatment room shall allow for continuous observation of the patient during irradiation, and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(15) Additional Requirements. In addition to the requirements of subdivision (14) of this subsection, any treatment room that contains a therapeutic radiation machine capable of operating above 150 kV shall meet the following requirements:

(A) All protective barriers shall be fixed except for entrance doors or beam interceptors;

(B) The control panel shall be located outside the treatment room or in a totally enclosed booth inside the room; and

(C) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, the exposure beam shall be terminated, and it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(16) Full Calibration Measurements.

(A) Full calibration of a therapeutic radiation machine subject to this subsection shall be performed by, or under the direct supervision of, an Authorized Medical Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine,

(ii) At intervals not exceeding twelve calendar months,

(iii) Before medical use under the following conditions:

(a) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled, and

(b) Following any component replacement, major repair or modification of components that could significantly affect the characteristics of the radiation beam, and

(iv) Notwithstanding the requirements of subparagraph (A)(iii) of this subdivision:

(a) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes or energies that are not within their acceptable range, and

(b) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in subparagraph (A)(iii) of this subdivision;

(B) To satisfy the requirement of subdivision (16)(A) of this subsection, full calibration shall include all measurements in the most recent recommendations for annual calibration of the NCRP or the AAPM; and

(C) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for both the therapeutic radiation machine and the X-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the Authorized Medical Physicist responsible for performing the calibration.

(17) Periodic Quality Assurance Checks. Each registrant shall perform periodic quality assurance checks on therapeutic radiation machines subject to this subsection that are capable of operation at greater than or equal to 50 kV, as follows:

(A) The registrant shall perform quality assurance checks in accordance with written procedures established by the Authorized Medical Physicist; and

(B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subdivision (16)(A) of this subsection. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subdivision (16)(A) of this subsection shall be stated;

(C) The cause for a parameter exceeding a tolerance set by the Authorized Medical Physicist shall be investigated and corrected before the system is used for patient irradiation;

(D) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Authorized Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in subdivision (16)(A) of this subsection;

(E) The registrant shall use the dosimetry system described in subsection (d)(3)(B) of this section to make the quality assurance check required in subparagraph (B) of this subdivision;

(F) The registrant shall have the Authorized Medical Physicist review and sign the results of each radiation output quality assurance check within one calendar month of the date that the check was performed;

(G) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this subsection are performed at intervals not to exceed one month;

(H) Notwithstanding the requirements of subparagraphs (F) and (G) of this subdivision, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks

required by subparagraphs (F) and (G) of this subdivision have been performed within the 30 day period immediately prior to said administration;

(I) To satisfy the requirement of subparagraph (G) of this subdivision, safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at each external beam radiation therapy room entrance,

(ii) The "BEAM-ON" and termination switches,

(iii) Beam condition indicator lights on the access door(s), control console and in the radiation therapy room,

(iv) Viewing systems, and

(v) If applicable, electrically operated treatment room doors from inside and outside the treatment room; and

(J) The registrant shall maintain a record of each quality assurance check required by this subdivision for five years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for each instrument used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(18) Operating Procedures. Each registrant shall operate any therapeutic radiation machine according to the following procedures:

(A) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subdivisions (16) and (17) of this subsection have been met;

(B) Therapeutic radiation machines shall not be left unattended during patient treatment unless secured pursuant to subdivision (9) of this subsection;

(C) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(D) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and an apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(E) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(F) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV unless conditions of section g (15) B are met. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of section 22a-153-2 of the Regulations of Connecticut State Agencies.

(19) Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with this subsection shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. Each survey instrument shall be operable and calibrated in accordance with subsection (h) of this section.

(h) Photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above). Each registrant shall operate photon therapy systems (500kV and above) and electron therapy systems (500keV and above) according to the requirements of this subsection.

(1) Possession of Survey Instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this subsection shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. Each survey instrument shall be operable and calibrated in accordance with subsection (i) of this section.

(2) Leakage radiation outside the maximum useful beam in photon and electron modes shall comply with the following requirements:

(A) The absorbed dose due to leakage radiation excluding neutrons at any point outside the maximum sized useful beam, but within a circular plane of radius two (2) meters that is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 cm^2 at a minimum of sixteen (16) points uniformly distributed in the plane;

(B) Except for the area defined in subparagraph (A) of this subdivision, the absorbed dose due to leakage radiation excluding neutrons at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 cm^2;

(C) For equipment manufactured after the effective date of this section, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1, as amended from time to time; and

(D) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subparagraphs (A) through (C) of this subdivision for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Commissioner.

(3) Leakage radiation through beam limiting devices shall comply with the following requirements:

(A) All adjustable or interchangeable beam limiting devices shall attenuate the radiation such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(i) A maximum of five (5) percent and average of two (2) percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven (7) centimeters outside the periphery of the useful beam, and

(ii) A maximum of ten percent (10%) of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two (2) centimeters outside the periphery of the useful beam but less than seven (7) centimeters outside the periphery of the useful beam.

(B) Measurement of leakage radiation shall be made as follows:

(i) Photon radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm^2), and

(ii) Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter (1 cm^2) suitably protected against radiation that has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

(4) Use of filters and wedges shall comply with the following requirements:

(A) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray, if permanently mounted to the tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be re-determined;

(B) If the absorbed dose rate information required by subdivision (9) of this subsection relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools; and

(C) For equipment manufactured after the effective date of this section that utilizes wedge filters, interchangeable field flattening filters or interchangeable beam scattering foils:

(i) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position,

(iii) A display shall be provided at the treatment control panel showing any wedge filters, interchangeable field flattening filters and interchangeable beam scattering foils in use, and

(iv) An interlock shall be provided to prevent irradiation if any filter or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out at the treatment control panel.

(5) Beam monitors. All therapeutic radiation machines subject to this subsection shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate, as follows:

(A) Equipment manufactured after the effective date of this section shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element;

(B) Equipment manufactured on or before the effective date of this section shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system; and

(C) The detector and the system into which that detector is incorporated shall meet the following requirements:

(i) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning,

(ii) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated,

(iii) Each beam monitoring system shall be capable of independently monitoring, interrupting and terminating irradiation,

(iv) For equipment manufactured after the effective date of this section, the design of the beam monitoring systems shall ensure that :

(a) Malfunction of one system shall not affect the correct functioning of any other system, and

(b) Failure of either system shall terminate irradiation or prevent the initiation of radiation, and

(v) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of this section, each display shall:

(a) Maintain a reading until intentionally reset,

(b) Have only one scale and no electrical or mechanical scale multiplying factors,

(c) Utilize a design such that increasing dose is displayed by increasing numbers, and

(d) In the event of power failure, the beam monitoring information required in subparagraph (C)(v)(c) of this subdivision displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

(6) Beam symmetry shall meet the following requirements:

(A) Bent-beam linear accelerators subject to this section shall be provided with auxiliary devices to monitor beam symmetry;

(B) The devices referenced in subparagraph (A) of this subdivision shall be able to detect field asymmetry greater than ten (10) percent; and

(C) The devices referenced in subparagraph (A) of this subdivision shall be configured to terminate irradiation if the specifications in subparagraph (B) of this subdivision cannot be maintained.

(7) Selection and display of dose monitor units shall meet the following requirements:

(A) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

(B) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation;

(C) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(D) For equipment manufactured after the effective date of this section, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

(8) Air kerma rate/absorbed dose rate. For equipment manufactured after the effective date of this section, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in subdivision (6) of this section may form part of this system. In addition:

(A) The dose monitor unit rate shall be displayed at the treatment control panel;

(B) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(C) If the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(D) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum leakage values. Records of these maximum values shall be maintained at the installation for inspection by the Commissioner.

(9) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy shall be performed as follows:

(A) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

(B) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen (15) percent or forty (40) dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(C) For equipment manufactured after the effective date of this section, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(10) Termination of irradiation. The operator shall be able to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(11) Interruption of irradiation. If a therapeutic radiation machine has an interrupt mode, the operator shall be able to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, the operator shall be able to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(12) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval, as follows:

(A) A timer shall be provided that has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

(B) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator; and

(C) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(13) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(A) Irradiation shall not be possible until a selection of radiation type, x-rays or electrons, has been made at the treatment control panel;

(B) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(C) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

(D) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

(E) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(F) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(14) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(A) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(B) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(C) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(D) For equipment manufactured after the effective date of this section, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1, as amended from time to time.

(15) Any therapeutic radiation machine capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(A) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(B) The mode of operation shall be displayed at the treatment control panel;

(C) An interlock system shall be provided to ensure that the equipment may operate only in the mode that has been selected;

(D) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(E) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after the effective date of this section:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of rotation or one (1) cm of linear motion differs by more than twenty percent (20%) from the selected value,

(ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent (5%) from the dose monitor unit value selected,

(iii) An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy,

(iv) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counter-clockwise moving beam radiation therapy, and

(v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;

(F) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by subdivision (10) of this subsection; and

(G) For equipment manufactured after the effective date of this section, an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy, or

(ii) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

(16) In addition to shielding adequate to meet requirements of subsection (i) of this section, each facility with a therapeutic radiation machine operating above 500 kV shall meet the design requirements of this subdivision:

(A) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(B) Control panel. In addition to other requirements specified in this section, the control panel shall also:

(i) Be located outside the treatment room,

(ii) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible,

(iii) Provide an indication of whether radiation is being produced, and

(iv) Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

(C) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(D) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(E) Room entrances. Treatment room entrances shall be provided with warning lights to indicate when the useful beam is "ON" and when it is "OFF." Such lights shall be in a readily observable position near the outside of all access doors;

(F) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(G) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with sections 22a-153-2(f)(1) and (2) of the Regulations of Connecticut State Agencies, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(H) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subdivision (11) of this subsection. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(I) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

(J) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten (10) MV prior to machining, removing or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(17) Each facility with a therapeutic radiation machine greater than or equal to 500 kV shall have Authorized Medical Physicist support as follows:

(A) The services of an Authorized Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Authorized Medical Physicist shall be responsible for:

(i) Full calibration(s) required by subdivision (20) of this subsection and protection surveys required by subsection (d)(1) of this section,

(ii) Supervision and review of dosimetry,

(iii) Beam data acquisition and transfer for computerized dosimetry and supervision of its use,

(iv) Quality assurance, including quality assurance check review required by subdivision (21)(E) of this subsection,

(v) Consultation with the authorized user in treatment planning, as needed, and

(vi) Perform calculations/assessments regarding medical events; and

(B) If the Authorized Medical Physicist is not a full-time employee of the registrant, the operating procedures required by subdivision (19) of this subsection shall also specifically address how the Authorized Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Authorized Medical Physicist can be contacted.

(18) Operating procedures.

(A) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(B) Therapeutic radiation machines shall not be made available for medical use unless the requirements of subsections (d)(1), (g)(20) and (g)(21) of this section have been met;

(C) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(E) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(F) A copy or the location of the current operating procedures shall be maintained at the therapeutic radiation machine control console. Emergency procedures shall be available at the therapeutic radiation machine control console.

(19) Acceptance testing, commissioning and full calibration measurements shall be performed in accordance with the auditing programs standards delineated in subsection (C)(13) of this section.

(A) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to this subsection shall be performed by, or under the direct supervision of, an Authorized Medical Physicist;

(B) Acceptance testing and commissioning shall be performed in accordance with the requirements specified and documented by an Authorized Medical Physicist and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(C) Full calibration shall include measurement of all parameters relevant to the clinical services provided at the facility. The Authorized Medical Physicist shall document this selection of relevant parameters. All parameters that are evaluated during the full calibration shall have action levels, which if exceeded, must have a specific course of action as delineated by the Authorized Medical Physicist. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters for all energies shall be completed at intervals not exceeding 12 calendar months.

(D) The Authorized Medical Physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits: Following any component replacement, major repair or modification of components that could significantly affect the characteristics of the radiation

beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in subparagraph (D)(i) of this subdivision; and

(E) Each registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the Authorized Medical Physicist responsible for performing the calibration.

(20) Each registrant shall perform periodic quality assurance checks in accordance with the auditing programs standards delineated in subsection (C)(13) of this section.

(A) Daily quality assurance checks shall be performed on all therapeutic radiation machines. The daily quality assurance checks may be performed under the direction of the Authorized Medical Physicist. The Authorized Medical Physicist shall document the selection of parameters requiring daily evaluation. All parameters that are evaluated during the daily quality assurance testing shall have action levels, which if exceeded, must have a specific course of action as delineated by the Authorized Medical Physicist.

(B) Monthly quality assurance checks shall be performed on all therapeutic radiation machines in accordance with the requirements specified and documented by the Authorized Medical Physicist. Monthly checks should be a subset of the full calibration checks. Monthly testing shall be performed by, or under the direct supervision of, an Authorized Medical Physicist.

(C) The registrant shall use an appropriate dosimetry system described in subsection (d)(3)(A) of this section to make the periodic quality assurance checks required in subparagraph (B) of this subdivision;

(D) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(i) The Authorized Medical Physicist shall be immediately notified if any parameter during daily quality assurance testing is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Authorized Medical Physicist has determined that all parameters are within their acceptable tolerances,

(ii) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by the Authorized Medical Physicist within ten business days, and

(iii) The Authorized Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals occurring once each calendar month;

(E) Therapeutic radiation machines subject to this subsection shall have additional safety quality assurance checks as deemed appropriate by the Authorized Medical Physicist performed at intervals specified by the Authorized Medical Physicist;

(F) To satisfy the requirement of subparagraph (C) of this subdivision, safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at each external beam radiation therapy room entrance,

(ii) Proper operation of the "BEAM-ON", interrupt and termination switches,

(iii) Beam condition indicator lights on the access doors, control console,

(iv) Viewing systems,

(v) Treatment room doors that are electrically operated from inside and outside the treatment room, and

(G) Each registrant shall promptly repair any system identified in subparagraph (G) of this subdivision that is not operating properly; and

(H) The registrant shall maintain a record of each quality assurance check required by subparagraphs (A) and (G) of this subdivision for five (5) years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for each instrument used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

(i) Each registrant shall ensure that survey instruments are calibrated as required by this subsection.

(1) Each registrant shall ensure that the survey instruments used to show compliance with this section have been calibrated before first use, at intervals not to exceed 12 calendar months, and following repair.

(2) Each registrant, or calibration service contracted by the registrant with the Authorized Medical Physicist's approval, shall:

(A) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and

(B) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty percent if a correction factor or graph is conspicuously attached to the instrument.

(3) Each registrant shall retain a record of each calibration required in subsection (i)(1) of this section for five (5) years.

(4) Each registrant may obtain the services of an ADCL or NVLAP accredited facility. Each registrant shall maintain records of calibrations that contain information required by subsection (i)(4) of this section.

(j) Each therapeutic radiation machine shall be provided with the following shielding and safety design requirements:

(1) Each therapeutic radiation machine subject to subsections (g) and (h) of this section shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with sections 22a-153-2(e) and (f) of the Regulations of Connecticut State Agencies.

(2) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted to the Commissioner for approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained **in Appendix A to Part X.**

(k) Requirements for the use of radiation therapy planning computer systems.

(1) The licensee shall ensure that an Authorized Medical Physicist performs acceptance testing of radiation therapy planning computer systems (TPS) prior to first clinical used, to verify the manufacturer's specifications.

(2) The licensee shall ensure that an Authorized Medical Physicist commissions the radiation therapy planning computer system prior to first clinical use. Commissioning includes input of all facility-specific data into the TPS, validation of the input parameters, and validation of the accuracy of computed doses, rendered treatment geometries and isocenter (or radioactive source) localization, for a sampling of such output parameters deemed by the Authorized Medical Physicist to be representative of the full range of clinical use at the licensee's facility. A complete report of all commissioning activities shall be made available for review.

(3) A subset of the commissioning tests, as deemed appropriate by the Authorized Medical Physicist, shall be performed at an interval of not greater than annually, or after any changes or upgrades to the treatment planning system's configuration.

(l) Requirements for treatment chart review.

(1) The Authorized Medical Physicist shall develop a chart review protocol for reviewing the accuracy of treatment delivery. At a minimum, this protocol shall require review of the following parameters where applicable: New or modified treatment fields, treatment prescription, simulation instructions, isodose distributions, special dose calculations and measurements, monitor unit calculations, in vivo dose measurements, treatment delivery records, and cumulative doses. If a computerized treatment verification system is used, the physics chart check protocol shall also include review of the following information in the computerized treatment verification system: treatment setup instructions, treatment field dose parameters and cumulative doses delivered.

(2) A chart review, following the protocol established in accordance with subsection (l)(1), shall be performed of each patient's chart to ensure accuracy of calculations, appropriateness of charting data and fulfillment of the physician's documented prescription. Any deviation in the delivered dose from the physician's documented prescription that exceeds the licensee's established reporting threshold or current applicable regulatory reporting thresholds should be reported to the responsible radiation oncologist for evaluation and potential corrective action. A chart review shall be conducted by or under the direct supervision of the Authorized Medical Physicist at least once every 7 consecutive days of clinical operation.

(3) Within one calendar month of the completion of each patient's treatment, the Authorized Medical Physicist shall review the entire patient treatment chart to affirm the fulfillment of the Authorized User's prescription dose.

Statement of purpose: This section establishes requirements for the use of therapeutic radiation machines.

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. All Therapeutic Radiation Machines.

A. Basic facility information including: name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic Radiation Machines up to 150 Kv (photons only). In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with Part D.201 of these regulations;

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where

it is likely that individuals may be present; and

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, please also identify the software used and the version/ revision date.

2. If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic Radiation Machines Over 150 kV.
In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [i.e.: photon, electron]. The target to isocenter distance shall be specified;

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze;

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron Shielding

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material;

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.